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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,184	12/19/2001	Chad Cori Huval	1932.1064-033	8481

21005 7590 03/27/2006

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EXAMINER	
WILLIAMS, LEONARD M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,184	HUVAL ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3 and 8-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 3 and 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Priority

The current application is a continuation of application 09/311103 now US Patent 6365186, which is a continuation-in-part of application 08/964536 now US Patent 6083497.

Response to Amendment/Arguments

Applicant's arguments with respect to claims 2, 3, and 8-10 have been considered but are moot in view of the new ground(s) of rejection.

This action is **non-final**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 3 and 8-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16, 22-25 and 27 of U.S. Patent No. 6365186. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are simply broader versions of patented claims 16, 22-25 and 27.

The instant claim 2 is drawn to a pharmaceutical composition comprising a unit dosage form of a polydiallylamine homopolymer, said homopolymer characterized in that the polymer is free of alkylated amine monomers, and a pharmaceutically acceptable carrier, wherein said homopolymer is crosslinked by means of a multifunctional crosslinking agent, and said crosslinking agent is present in an amount from about 2.5-20% weight, based upon the combined weight of monomer and crosslinking agent. Instant claim 3 further limits claim 2 wherein the polymer is crosslinked using epichlorohydrin. Instant claim 8 is an independent claim that is identical to claim 2, wherein the limitation "...wherein the unit dosage form is a capsule..." is added at the end of the claim. Instant claim 9 limits claim 2 wherein the polydiallylamine homopolymer is in the free base form. Instant claim 10 limits claim 2 wherein the polydiallylamine homopolymer is a salt or partial salt.

Claim 16 of the '186 patent is drawn to a pharmaceutical composition comprising: a) a first amount of an unsubstituted polydiallylamine polymer; b) a second amount of a cholesterol-lowering agent; and c) optionally, a pharmaceutically acceptable carrier.

Claim 22 of the '186 patent further limits claim 16 wherein the unsubstituted polydiallylamine is characteized by one or more monomeric units of the formula; (I) (II) or a combination thereof and salts thereof (wherein the structures of formula I and II are identical to the monomeric units of the current application as detailed in the specification). Claim 23 further limits claim 16 wherein said plymer is crosslinked by means of a multifunctional crosslinking agent, said agent being present in an amount from about 0.5-50% by weight, based upon the combined weight of monomer and crosslinking agent. Claim 24 further limits claim 23 wherein said crosslinking agent is present in an amount from about 2.5-20% by weight. Claim 25 further limits claim 23 wherein said crosslinking agent comprises epichlorohydrin. Claim 27 further limits claim 16 wherein the polymer is a homopolymer.

The difference between the instantly claimed pharmaceutical composition and the pharmaceutical composition detailed in the '186 patent is that the '186 patent included the polydiallylamine homopolymer, a second cholesterol-lowering agent and optionally a pharmaceutically acceptable carrier, while the currently claimed invention is directed only to the polydiallylamine homopolymer. As the currently claimed pharmaceutical composition includes open language (comprising) it encompasses the pharmaceutical composition of the '186 patent, and is thus simply a broader version of the patent claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2,3 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keim et al. (US Patent No. 3700623) in view of Holmes-Farley et al. (UA Patent No. 6203785).

Keim et al. teach in col. 1 line 50 to col. 3 line 62, water-soluble resionous linear polymers of formula I where the R and R' can be H, wherein the polymers are synthesized by reaction of the hydrohalide salt of a diallylamine (formula II) with other copolymerizable ingredients, in the presence of a free radical catalyst to give the free base. The polymers can be homo or hetero polymers and can be crosslinked by reaction with an epihalohydrin, preferably epichlorohydrin in amounts of from 0.5 mole to 1.5 mole compared to amine.

Keim et al. does not teach the polymers for use in pharmaceutical compositions.

Holmes-Farley et al. teach, col. 1 line 45 to col. 2 line 3, polymers for use as bile acid sequestrants wherein the polymers can comprise secondary, tertiary or quartenary amino groups, or combinations thereof, either as a pharmaceutically acceprtable acid or free base, can be linear or cross-linked and can comprise poly(diallylamine) polymers as either homo or hetero polymers. In col. 6 lines 17-56, Holmes-Farley et al. teach that the compositions can be formulated as pills, tablets, capsules and powders, with the polymers being administered alone or in combination and the polymers can be crosslinked by including a multifunctional co-monomer as the crosslinking agent, wherein the crosslinking agent is added in amounts between 1-25% by weight, and preferably 2.5-20% by weight.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the diallylamine polymers of Keim et al. in order to formulate pharmaceutical compositions as Keim et al. details the synthesis of such polymers as homopolymers, crosslinked via chlorohydrin, and Holmes-Farley et al. indicate that

diallylamine crosslinked homopolymers have been used to formulate pharmaceutical compositions for use in methods of sequestering bile acids. One would have been motivated to use the multifunctional crosslinking agent epichlorohydrin in amounts of 2.5-20% by weight, in the synthesis of the pharmaceutical compositions, as Keim et al. indicated epichlorohydrin as a suitable crosslinking agent and Holmes-Farley et al. suggests use of crosslinking agents in amounts of 2.5-20% by weight.

The examiner respectfully points out the following: "Products of identical chemical composition can not have mutually exclusive properties. "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claimsare necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Conclusion

No claims are allowable.

This action is **non-final**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW